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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|---------------------------|---------------------|------------------|
| 10/509,952      | 10/04/2004  | Reddy Bandi Parthasaradhi | H1089/20015         | 3097             |

3000 7590 01/17/2008  
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PHILADELPHIA, PA 19103-2212

EXAMINER

CHANG, CELIA C

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1625

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

01/17/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/509,952 | <b>Applicant(s)</b><br>PARTHASARADHI ET AL. |  |
|                              | <b>Examiner</b><br>Celia Chang       | <b>Art Unit</b><br>1625                     |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Response filed by applicants dated Nov. 9, 2007 has been considered carefully.  
Claim 1-4 are pending. No amendment was made.

2. The rejection of claims 1 and 4 under 35 USC 102(e) over US 6,649,765 is maintained for reason of record.

Applicants argued that the term "concentration" is removal of solvents, therefore, the solvents of the prior art process is methylene dichloride, then, methanol not methylene dichloride with methanol. Applicants argued that the default description of a solid material is not inherently "amorphous".

Two chemical handbook are hereby attached for applicants convenience. The CRC handbook defines amorphous as "having no definite order of crystalline structure". Therefore, if a solid was not defined to have "definitive crystalline order" is amorphous. The Hackh's chemical dictionary is provided to show that the term "concentrate" chemically is the increase of solute content, thus, *not removal of all solvent*.

The mis-interpretation of the terms by attorney is improper. The rejection is proper and maintained for the printed reference read on the claims.

3. The rejection of claims 1-4 under 35 USC 103(a) over Vijayadhar et al. '765 in view of Imai '864 or over Sugimoto et al. '841 or Vijayadhar et al. '765 or Imai in view of Lieberman and Brittain are maintained for reason of record.

The previous office action dated Aug. 7, 2007 provided:

--*teaching* from the art that donepezil hydrochloride is soluble in chlorinated solvent and alcohol specifically, methylene chloride and methanol;

--*suggestion* that spray dry a pharmaceutical product using a soluble solvent and spray drying procedure would produce an amorphous material;

--*motivation* that an amorphous material would give better dissolution.

Therefore, every element required by the KSR guideline has been provided. Applicants provided no factual evidence that why a process employed a simultaneously co-existed mixture


of chlorinated solvent and alcohol would produce an amorphous material which is different from the noncrystalline solid found in the prior art using a stepwise introduced dichloromethane and methanol solvents, when both solvents are known to dissolve donopezil hydrochloride.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jan. 14, 2008

  
Celia Chang  
Primary Examiner  
Art Unit 1625